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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 09/671,106 09/28/2000 Randal K. Buddington 2343-104-27 8636 7590 08/12/2003 **Patent Prosecution Services EXAMINER** Piper Marbury Rudnick & Wolfe LLP EVANS, CHARESSE L 1200 Nineteenth Street, N.W. Washington, DC 20036-2412 ART UNIT PAPER NUMBER 1615 DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/671,106	BUDDINGTON ET AL.
Office Action Summary	Examiner	Art Unit
The MAILING DATE of this communication and	Charesse L. Evans	1615
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status		
1) Responsive to communication(s) filed on <u>15 April 2003</u> .		
2a)☐ This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 16-20 and 22-24 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>16-20 and 22-24</u> is/are rejected.		
7)☐ Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) eatent Application (PTO-152)

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#### **DETAILED ACTION**

### Action Summary

Acknowledgement is made of the receipt of applicant's amendment and remarks, filed April 15, 2003.

The rejection of record of claim 20 under 35 USC 112, second paragraph, is withdrawn.

Claims 16-20 and 22-24 are pending in this action.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 16, 17, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul et al (US 6,241,983 B1). Claims 20, 16, 17, and 22 are directed to a method for the inhibition or treatment of systemic infections in humans by the administration of a composition comprised of a fermentable dietary fiber or a mixture of fermentable

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dietary fibers, wherein the composition is administered orally or through tube feeding. Paul teaches an orally administered composition for promoting gastrointestinal health comprised of an effective amount of dietary fiber (Abstract and Column 3, lines 39-57). The dietary fiber is a member selected from the group consisting of fructooligosaccharides, such as inulin, pectins and pectic polysaccharides, and mannans such as guar gum (column 4, lines 1-10). The referenced composition can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as E.coli, Salmonella and Candida (column 16, lines 21-26). Paul reads on each and every aspect of the above-referenced claims. Thus, Paul anticipates claims 20, 16, 17, and 22.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al (US 6,241,983 B1) in view of Van Loo et al (US 6,500,805 B2). In view of the 102 discussion above, the claims are further directed to the degree

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of polymerization of the fiber of at least 25, administered in the amount of 5-40 mg/day.

Van Loo et al teaches a fructan-containing composition with an average degree of polymerization of 15 or higher (column 4, lines 22-28 and claim 1). Van Loo discloses chicory inulin with an average degree of polymerization of about 25 (claim 18). The daily doses effective in providing prevention against disease states such as colon cancer, range from 0.01 to 2g/kg body weight (column 5, lines 51-54). While the reference does not expressly teach applicant's claimed daily dosage amount, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Accordingly, it would have been obvious to one of ordinary skill in the art to utilize the amounts as suggested by Van Loo, in order to optimize the beneficial effects of the composition.

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Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday-Thursday 7:00a -4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans

Examiner

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August 9, 2003